

REMARKS / ARGUMENTS

Claims 1-26, 28-30, 32, 34, 38-44 remain in this application. Claims 27, 31, 33, 35-37 have been cancelled. All claims stand rejected. Claim 39 has been amended to delete an unnecessary phrase.

1. Headings in the Specification

The specification has been amended to include headings as suggested in the guidelines set forth in 37 CFR 1.77(b). In light of this, withdrawal of the objection based on this ground is requested.

2. Drawings Show Claim Elements

Claims 27, 31, 33, 35-37 have been cancelled. Replacement Figure 4 depicts a transducer (40), which may the amendments to the figure specify that the transducer for example is a pressure, airflow, temperature, moisture, oxygen and/or carbon dioxide sensor. The electronic information processor is depicted as microcontroller (50) which communicates with a memory (60). The memory (60) i.e., an “active memory” (as depicted by two way arrows), which may include predictive algorithm(s), look up table(s), and/or dose memory components, as depicted in Replacement Fig. 4. The selector is depicted (11) in Replacement Figure 4. The energy store is depicted as the contents of canister (2) in Fig 2. The release counter is shown as user display 30 (dose counter) in Fig. 4. The specification on page 9 has been amended to reflect the amendments to the drawings. No new matter is added by virtue of the replacement drawing, support for these amendments being found in the claims as originally filed, and at page 4, lines 14-26; page 5, line 1-15. It is submitted that the drawings amply depict the claimed subject matter to the extent necessary to allow one of ordinary skill to understand and practice the claimed invention.

3. Claims are Non-obvious as One of Ordinary Skill would not be Motivated to modify Goodman As Suggested by the Examiner

The Examiner opines that the pending claims are obvious due to GOODMAN (US 5404871) in view of HILLSMAN (US 4,984,158). Applicant respectfully traverses this rejection.

The Examiner acknowledges there is no disclosure in GOODMAN of the inhaler disclosed therein having a monitor which provides a signal, to an actuator, at a trigger point which is correlated to the end of the exhalation part of a patient's breath cycle (the actuator, in response to the signal, actuating a release mechanism of a medicament container to release medicament from the container), as required by the pending claims of the present application. This is because GOODMAN advocates identifying an optimal point during inspiration of a patient to deliver medicament (e.g. col. 5, lines. 16-18 and 25-28; col. 22, ll. 24-31).

Goodman indicates that a "major problem with metered dose inhalers is that the patient frequently actuates the device at the incorrect time during inspiratory flow to obtain the benefits of the intended drug therapy, e.g., too early or too late in the flow cycle or during expiration." (Col. 1, lines 34-38). Goodman targets a delivery point in the inspiratory period of the flow cycle as optimal, defining the "delivery point" as "a point in the detected inspiratory flow at which an amount of aerosol is to be delivered." (col.6, lines 55-57). Moreover, Goodman teaches that pulsing doses during inhalation beneficially increases the respirable fraction of medicament delivered to the lung. (col. 17 lines 26-33; col. 25, line 45- col. 26, line 13; and col. 29, lines 58-63, p. 35, lines 21-46).

The Examiner considers that it would have been a mere routine step, at the priority date of the application, for the person of ordinary skill in the art to modify the GOODMAN inhaler to read on the pending claims based on the disclosure in HILLSMAN. HILLSMAN describes an aid training a patient to use a patient activated MDI, wherein the aid will educate the patient on proper breathing technique using biofeedback (p. 2,

lines 13-20), to exhale beyond a point where the patient normally would (col.4, lines 15-23), to activate a device simultaneously with, or alternatively, just before or just after, the aerosol is released from the MDI (col. 5, lines 6-14). HILLMAN, however, points out that “[w]hile it is generally felt that timing of MDI activation should be simultaneous with the beginning of inspiration, there is a minority scientific opinion that questions whether said activation should be a fraction of a second before or after the beginning of inspiration. However, it is understood that these events are substantially concurrent. (col. 1, line 65- col. 2, line 3).

Bearing in mind that the skilled person is taken to have no inventive capacity, as a simple matter of principal a combination of GOODMAN and HILLSMAN is only admissible if one of these documents would have provided the skilled person with a clear motivation to make the combination.

In the present application at page 2, paragraph 1 (see parent case WO-A-00/53247) the state of the art for the claimed invention is disclosed in the following terms:-

Breath-actuatable or breath-assisted inhalation devices have been developed to address the needs of patients having poor co-ordination skills and/or unreliable breath capability. Such devices typically have a breath trigger mechanism which triggers release of medicament in response to the inward breath of a patient.(Emphasis added)

Thus, the GOODMAN disclosure forms part of a more general teaching in the art to deliver medicament during the inspiratory part of a patient's breath cycle. The skilled person would therefore have had to go against this tide of thinking in the art to adapt the GOODMAN inhaler to fall within the scope of the pending claims.

HILLSMAN would not have provided the unimaginative skilled person with the catalyst to swim against this tide as HILLSMAN is concerned with a training apparatus for training a patient to use an inhaler in which the release mechanism of the medicament container has to be manually operated (e.g. col. 2, lines 38-45). GOODMAN, by

contrast, has a breath-triggered actuator for this task. Hence, GOODMAN ascribes maximal benefit through a calibrated breath actuated device, which in a preferred state is activated by an inhalation, and pulses medicament into the inward flow of the patients breath.

When due account is taken of this fundamental difference, it becomes clear that the skilled person would not have modified GOODMAN in the manner suggested by the Examiner. To do so would go against the express teaching of GOODMAN, and the general teaching in the art, based on a document which does not relate to a breath-operated inhaler (BOI).

In fact, the disclosure in HILLSMAN is rendered redundant by BOIs of the type disclosed in GOODMAN because BOIs dispense with the need for a training apparatus to coordinate manual actuation with a breath cycle, and GOODMAN would have reflected a further progress in the respiratory field in the years that passed since the filing of HILLSMAN. The BOI automatically releases the medicament at a predetermined point in the inward breath cycle.

It is therefore also submitted that the skilled person would not look to modify the operation of the BOI in GOODMAN based on a disclosure in HILLSMAN relating to an inhaler system rendered redundant by GOODMAN.

In conclusion, there is no credible justification for the skilled person to have considered modifying the GOODMAN inhaler based on the disclosure in HILLSMAN. To find otherwise can only be based on hindsight of the claimed invention.

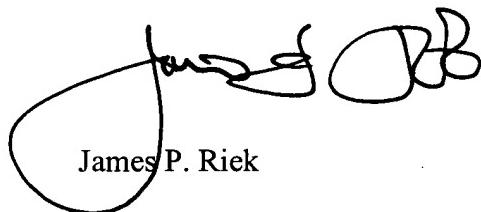
CONCLUSION

The objections to the specification and drawings have been overcome through the amendments and arguments made herein. For the reasons provided above GOODMAN, in view of HILLSMAN does render obvious the claims presented herein.

In light of these amendments and arguments, all issued raised by the examiner to date have been addressed. As such, the claims are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,



A handwritten signature in black ink, appearing to read "James P. Riek". The signature is fluid and cursive, with a large, stylized 'J' at the beginning.

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